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## **An Audit on Virological Efficacy of Anti-Retroviral Therapy in a Specialist Infectious Disease Clinic**

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### **Abstract**

We have assessed the efficacy of anti retroviral therapy (ART) using undetectable viral load (VL) (<50 RNA copies/ml) as a marker of virological success, in patients who have Human Immunodeficiency Virus (HIV) attending the Department of Infectious Disease. A cross-sectional review of patients' case notes was used to obtain their demographics and treatment details. 79% (253) of the hospital case notes of clinic population was available for analysis, which represents 90% of those receiving ART in the clinic. 166/253 of the cohort were receiving treatment at the time of this study and 95% (157/166) of these were on treatment for greater than 6 months. The total virological success rate is 93%, which is comparable to other centres and are as good as those from published clinical trials. 56% of those on therapy who have virological failure were Intravenous Drug Users (IVDUs). Case by case investigation for those with treatment failure is warranted.

### **Introduction**

Despite advances in the pharmacology of anti retroviral therapy (ART), how they are utilised varies widely and thus measured outcomes can be diverse<sup>1</sup>. The role of a clinical audit is to evaluate and compare results with standard accepted practice and to highlight any shortcomings and areas that may be improved (National Institute of Clinical Excellence 2002). As a review of our quality of care we have assessed our use of ART using undetectable viral load (VL) (<50 RNA copies/ml) as a marker of virological success. The results of this audit can therefore be used to highlight current shortcomings in practice, to guide future practice and to encourage further research.

### **Methods**

All (Human Immunodeficiency Virus) HIV positive patients attending the infectious disease clinic were identified from a card index file. A cross-sectional chart review was carried out recording their variables in a data base. Patients who have passed away or are currently being followed up by other centres were excluded from this audit. The data was obtained directly from each patient's hospital case notes, which included patients' demographics (Table 1) and their treatment details, VL in last 4 visits, latest CD4 counts, current and past ART regimens details.

Success of treatment was defined as patients with a VL < 50 copies/ml at the point of last measurement of HIV VL. Prevalence of viral load suppression < 50 copies/ml was recorded from the most recent clinic attendance. Those on treatment with a viral load >50-<400 copies/ml had their previous 3 viral loads also recorded to identify recent patterns to differentiate between viral load blips, declining viral loads and true virological failure. Sub-analysis was conducted on different groups as outlined below; (a) Treatment naïve patients i.e. patients that have never been on antiretroviral therapy. (b) Patients that are currently off treatment but who were on treatment in the past, i.e. the 'On Off treatment' group. (c) Patients that started therapy for the first time less than six months ago i.e. < 6 months on treatment. (d) Patients that have been on therapy for greater than six months i.e. > 6 months on treatment.

### **Results**

Seventy nine percent (253/320) of the population had hospital case notes available for analysis. This captured 90% of those who are on ART (166/185).

#### *General clinic demographics (Table 1)*

The general demographics of the HIV clinic reveal a fairly equal gender divide with 49% men and 51% women. Diversity is reflected by the 29 different Nationalities attending the clinic. Patients were divided into those from Africa (50%, of which the biggest group, 28% are Nigerian) and those from Europe (49%, 89% of these are Irish) with a very small minority (1%) from Asia. The majority of patients are between 30 and 50 years of age (74%). The most likely mode of transmission was the heterosexual route - 56%. However only 39% of the European population cited the heterosexual route compared with 79% of the the African population. The other main transmission routes in the European population were intravenous drug use (IVDU) 26% and men who have sex with men

(MSM) 22%. The average time since first diagnosis of HIV was 5.5 yrs. In relation to the Irish population 65% were male and most were between the ages of 40-49 years (45%). The most likely mode of transmission was heterosexual (41%). Most of the patients within the Irish heterosexual category were female (58%).

#### *Treatment Naïve Group*

58/87 of the patients off therapy were treatment naïve. An average person in the treatment naïve group would be an African Hetrosexual male between the ages of =19-29 years who has recently been diagnosed. The CD4 counts in the treatment naïve group demonstrated that 68% of this group have CD4 counts greater than 350/ $\mu$ L and therefore treatment is not warranted. However 29% in this group have CD4 counts between 200-350/ $\mu$ L and these patients should be closely monitored so that treatment is initiated before advanced immuno-suppression occurs. Indeed these patients are recalled for monthly check-ups to the clinic. Significantly there were no patients in the treatment naïve group that had CD4 counts less than 200/ $\mu$ L (Table 2).

#### *On-Off Treatment Group*

In the on-off treatment group (29 patients) there was a much higher percentage of African, female gender, and the age group below 40 years. 65% of the patients in this group were receiving ART medication during pregnancy to prevent mother to child transmission and medication was stopped postpartum. In the on-off treatment group 62% of patients had CD4 counts >350/ $\mu$ L and so treatment was not required. 17% in this group have CD4 counts between 200-349/ $\mu$ L and these patients must be monitored closely. 21% (6 patients) have CD4 levels less than 200/ $\mu$ L. According to accepted guidelines these patients should be on treatment. A third of these patients is intravenous drug users and has poor compliance recorded in their charts. The remaining scenarios were equally divided between, postpartum, drug resistance, patient preference to stop medication and one for unknown reasons (Table 3).

#### *<6 months of Tx*

The average person in this group is an African hetrosexual male between the ages of 20 and 30. There were 9 patients audited who had started treatment in the last 6 months. Of these, one patient achieved virological suppression with a viral load of less than 50 copies/mL. It is difficult to interpret this data accurately as many of the patients in this group had only started their regimens some weeks ago. A longer follow up period is required to accurately assess their viral loads.

#### *>6 months of Tx*

An average person in this group is a European heterosexual man greater than 40 years of age. There were 157 patients on treatment for greater than 6 months (Table 4). Virological success was achieved in 83% of cases. 15/16 patients with viral loads between >50-<400 copies/mL, had either declining viral loads or a once off blip in results that on follow up would be expected to reach viral suppression. Thus the overall rate of virological success can be taken as 93%. One patient in this group was in true virological failure where the previous 3 viral loads reflected a consistent increase in the viral load levels.

33 patients were taking the LTAR regimen (Lamivudine/Tenovofir/Atazanavir /Ritonavir). There are 34 other different regimens in use in the clinic. Nine of the patients that were on treatment had viral loads of >1,000 copies/mL, treatment has failed in these cases. Five of these were intravenous drug users and with poor compliance recorded. Mode of transmission for one of these patients was the vertically acquired route and drug resistance may have been a factor here.

### **Discussion**

One of the findings of this audit is the demographical differences between the European and African populations. The European patients are generally older and constitute the majority in the 'treatment for more than six months' category. The older European population may be due to successful treatment regimens and effective public health HIV prevention campaigns. In Ireland regarding future HIV prevention campaigns it is worth noting that the majority (41%) of the Irish population acquired HIV by the heterosexual route. The African population are generally younger and predominate in the 'treatment naïve' and in the '<6 months Tx' categories. This may be explained by the earlier detection rates in the African population as part of current refugee screening policies so that the African population may be over represented.

The fact that none of the patients in the 'treatment naïve' category had CD4 count <200/μL reflects the efficiency of the clinic in identifying patients that require treatment. It is only within the 'on-off treatment' category that CD4 counts <200/μL exist. In this group, treatment was offered to patients and for reasons such as poor compliance, patient preference, and the development of resistance these patients are not currently on medication. Our total virological success rate of 93% compares favourably with similar published audit results (Curtis et al 2003<sup>2</sup> - 58.9% had VL<50copies/ml, Madge et al 2008<sup>3</sup> - 92% had VL<50copies/ml).

The use of 35 different regimens in the clinic reflects how essential it is to tailor therapy to the individual's needs. This would have contributed greatly to our high virological success rate. With 33/166 patients receiving the LTAR 1st line regimen, further analysis may be useful in comparing this with other regimens used in other clinics. Over half of those with virological failure despite being on treatment for greater than six months, reported 'IVDU' as the mode of transmission. Poor compliance was recorded in these cases. Despite a multidisciplinary approach to care in the HIV clinic perhaps an early more targeted holistic approach for this subset of patients would be beneficial such as the inclusion of specialist addiction counsellors. A further case by case investigation for those with treatment failure is warranted and their eligibility for alternative classes of ART e.g. fusion inhibitors<sup>4</sup> should be considered.

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